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| 09/987,776      | 11/16/2001  | Peter Van Dam        | P-9123              | 7723             |

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MEDTRONIC, INC.  
710 MEDTRONIC PARKWAY NE  
MS-LC340  
MINNEAPOLIS, MN 55432-5604

EXAMINER

SCHAETZLE, KENNEDY

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3762

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/987,776

Applicant(s)

DAM, PETER VAN

Examiner

Kennedy Schaetzle

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-19 is/are allowed.
- 6) ☒ Claim(s) 1,3,6-10,20-28,30-35,42-47 and 49 is/are rejected.
- 7) ☒ Claim(s) 2,4,5,11,12,29,36-41,48,50 and 51 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4.6.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Claim Objections*

1. Claim 26 is objected to because of the following informalities: the phrase "...comprising the slope of said signal..." on line 1 is grammatically awkward (the examiner will assume the word "determining" was intended to be inserted after the word "comprising"). Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 6-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 6, it is not clear which QT interval is being referred to on line 5 (i.e., whether it is the evoked QT interval just previously mentioned or the intrinsic QT interval discussed in parent claim 1). The examiner will assume the former when interpreting the claim on the merits.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Berger (Pat. No. 5,560,368).

Regarding claim 20, Berger discloses a method of obtaining intrinsic QT data comprising the steps of receiving patient QRST signals (note col. 6, lines 36-61 and the ECG shown in Fig. 1), determining when an intrinsic R wave has occurred (note col. 8, lines 23-25), initiating a T wave measuring operation after the occurrence of a said R

wave (note col. 5, lines 41-48), carrying out the measuring in accordance with a predetermined algorithm (note col. 10, lines 40-48) and comparing the resultant measure with at least one predetermined criterion (the template) to detect the occurrence of a T wave and determining the time of a predetermined characteristic of the received signal (T wave endpoint) that is detected as a T wave (note col. 12, lines 55-59), and obtaining a value of QT as the time from the intrinsic R wave to the characteristic time (the inherent definition of what a QT interval is).

The method disclosed by Berger does not require pacing to evoke an R wave or T wave, and therefore lacking any artificial stimulus, such waves would inherently be intrinsic.

It should also be noted that Berger teaches that the invention may be applicable to pacing and defibrillating devices without any modification (note col. 10, lines 39-60).

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 3, 21-28, 30-35, 42-47 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berger (Pat. No. 5,560,368) in view of Begemann et al. (Pat. No. 4,972,834).

Regarding the application of Berger to claim 1, note the comments made in the rejection of claim 20 above. Berger does not explicitly state that the intrinsic QT interval determined by his invention can be used to provide pacing control for a rate responsive pacer. Berger, however, does state that the algorithm presented may be employed in pacer devices such as those that already employ the QT interval to regulate pacing rate (note col. 10, lines 39-60). To utilize the particular QT interval measuring algorithm of Berger in a device that also requires the same information, would have therefore been

considered obvious by those of ordinary skill in the art. A QT interval is a QT interval regardless of the method used to obtain it. Begemann et al. disclose such a pacer/lead system wherein the rate of pacing is controlled by the monitored QT interval via a QT reference curve. As information pertaining to malignant arrhythmias would be considered very useful to any device whose function is to treat arrhythmias, those of ordinary skill in the art would have seen the obviousness of incorporating the QT interval detection algorithm defined by Berger into the device of Begemann et al. as such a system would not only allow the measurement of the required QT interval for pacing rate control, but also allow for the assessment of risk for cardiac arrhythmias, sudden cardiac death, congestive heart failure, etc..

Regarding claim 3, the examiner takes Official Notice that it is old and well known in the signal processing arts to compare cardiac signals by integrating the signal over a set time period and comparing the area under the curve with a predetermined area threshold quantity in order to ascertain valid signals from noise. To utilize known signal processing techniques in the invention of Berger as further defined by Begemann et al. would have therefore been considered obvious by those of ordinary skill in the data processing arts. A related comment applies to claims 21, 23 and 33-35.

Regarding claims 22 and 32, those of ordinary skill in the art would have considered the initiation of a T wave measuring operation a predetermined time after an intrinsic R wave to be obvious given that it would be pointless to initiate such an operation immediately subsequent an R wave since the T wave would not be expected at this time. The use of timing windows to initiate device processing operations when the signal of interest is most likely to occur, is a matter of good design to avoid the needless expenditure of battery power—an important consideration in any medical implant device.

Regarding claims 24, 25 and 46, note the QT interval/ pacing rate curve of Begemann et al.. Such a stored curve is a standard tool for controlling pacer rate in rate-responsive devices utilizing the QT interval.

Concerning claims 26, 31 and 45, the examiner takes Official Notice that the detection of signal slope maximum is a common technique used to ascertain the rising

or falling edges of a signal, and can thus be used to identify a fiducial point for the purposes of establishing a reference point(s) from which to consistently base time measurements.

Regarding independent claim 27, comments parallel to those made in the rejection of claim 1 apply here as well.

Regarding independent claim 42, comments parallel to those made in the rejection of claim 1 apply here as well.

Regarding claim 43, the examiner considers the template of Berger to represent predetermined stored T wave criteria.

Concerning claim 44, note the discussion of related claims 22 and 32 above.

Regarding claim 47, artisans Begemann et al. disclose reference means for calculating a QT reference curve as shown for example in Fig. 2 and discussed in the algorithm flow charts.

Concerning claim 49, as the method of Berger does not distinguish between evoked and intrinsic activity, it is inherent that it is capable of determining the QT interval of evoked beats just as well as it can determine the QT interval of intrinsic beats.

#### ***Allowable Subject Matter***

8. Claims 2, 4, 5, 11, 12, 29, 36-41, 48, 50 and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In regards to claim 2, the prior art of record does not appear to disclose the use of the recited comparing and data means that are operative at rates above the maximum sensor rate.

Regarding claim 4 and claims with similar limitations, the prior art of record does not teach to compensate for evoked QT interval data to account for the differences between evoked and intrinsic QT intervals.

Regarding claim 11, the prior art does not teach to set the sensor rate to "unknown" for any detected ectopic beat.

Regarding claims 29 and 48, the prior art does not teach to detect ectopic beats and inhibit the determination and storing of a QT value for such a beat.

9. Claims 6-10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Regarding claim 6, the prior art does not appear to teach calculating sensor rate as a function of both said intrinsic QT reference curve and the evoked QT interval (note the comments made above in the rejection of this claim under 35 U.S.C. §112, 2<sup>nd</sup> paragraph).

10. Claims 13-19 are allowed.

The recited compensating means of claim 13 does not appear to be disclosed by prior artisans.

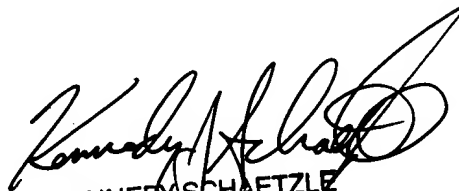
### ***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS  
March 20, 2004

  
KENNEDY SCHAETZLE  
PRIMARY EXAMINER